MEMORANDUM

TO: DENTAL PRODUCTS PANEL MEMBER/CONSULTANT

FROM: MICHAEL E. ADJODHA, SCIENTIFIC REVIEWER, DENTAL DEVICES BRANCH, FDA

SUBJECT: PETITION AND INFORMATION TO BE DISCUSSED AT THE MAY 22, 2003, MEETING

DATE: 5/9/2003

Dear Dental Products Panel Member/Consultant:

Thank you for agreeing to serve at our next meeting of the Dental Products Panel on May 22, 2003. The subject of the meeting will be reclassification of tricalcium phosphate. This reclassification is based on a petition the FDA received to reclassify tricalcium phosphate from Class III (Premarket Approval) to Class II (Special Controls). Tricalcium phosphate is currently regulated for dental indications as a Class III device under 21 CFR 872.3930, "tricalcium phosphate granules for dental bone repair." A petition from Bicon, Inc., was recently submitted requesting that tricalcium phosphate be reclassified into Class II because, among other reasons stated in the petition, it is regulated as such for orthopedic indications and has a twenty-year history of use.

Please review the enclosed petition and other materials in preparation for the meeting. The focus of the meeting will be whether it is appropriate to reclassify tricalcium phosphate from its current classification and, if so, considering the risks of the device, what special controls would be needed to provide a reasonable assurance of safety and effectiveness.

You will be asked at the end of the meeting to reclassify the device by filling out a "General Device Classification Questionnaire" and a "Supplemental Data Sheet." These forms will provide for us your formal classification recommendation. Copies of these forms are provided for your reference. Please do not complete them until the meeting.

Also provided, for reference, is a copy of a guidance document developed by the Restorative Devices Branch for their calcium salt bone fillers. There is currently no guidance for these devices for dental indications. The recommendations you provide to us at the meeting will be helpful in formulating a future dental guidance for calcium phosphate bone void fillers.

Also included in this package are:

- ?? The questions for the panel to consider,
- ?? A review of the petition by the FDA lead reviewer,
- ?? The adverse event reports on tricalcium phosphate, and

?? A draft agenda for the meeting.

?? A sample guidance document from the Restorative Devices Branch

If you have any questions or concerns, please contact me at 301-827-5283, ext. 123. or via email at: mea@cdrh.fda.gov. Once again, thank you for agreeing to share your expertise with us.

RECLASSIFICATION OF 21 CFR 872.3930

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(For Reference)

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(For Reference)